DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 2005

Mr. Fray Adib
President
Myotronics-Noromed, Incorporated
15425 53rd Ave South
Tukwila, Washington 98188

Re: K040400
Trade/Device Name: Myo-trode SG Disposable Electrodes
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: II
Product Code: NUW
Dated: June 2,2004
Received: June 4,2004

Dear Mr. Adib:

This letter corrects our substantially equivalent letter of July 20, 2004, regarding the classification of your device which was incorrectly identified as "unclassified."

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent, for the indications for use stated in the enclosure, to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

iu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K-040400

Device Name: Myo-trode SG Electrodes

Indications for Use:

As a disposable, adhesive, conductive interface between a patient's skin and muscle stimulating devices manufactured by Myotronics-Noromed, Inc. including the Models 54, JS, and BNS-40.

Prescription Use XX **OR Over-The-Counter Use** _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PACE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control. Dental Devices

510(k) Number K040400

JUL 2 0 2004

510(k) SUMMARY OF SAFETY & EFFECTIVENESS

Myo-trode SG Electrodes, 510(k) # K-040400

This summary of safety and effectiveness information is submitted in accordance with the requirements of 21CFR 807.92(c)

Submitter: Myotronics-Noromed, Inc.
15425 – 53rd Avenue South
Tukwila, WA 98188
Telephone (206) 243-4214
Contact: Mr. Fray Adib, President

Date Prepared: February 10, 2004 (Revised July 6, 2004)

Device Name: Myo-trode SG disposable, adhesive, electrodes

Common name: Muscle monitoring devices, accessory

Classification: Unclassified, Product code KZM

Predicate devices: Lead-Lok neurostimulation electrodes, K010431, Uni-Patch TENS Electrodes, K961141, Myotrodes II, K921498, Model BNS-40, K842224/A, Model J-4, K842223, Model J-5, K031998

Description of the Device: A disposable cutaneous TENS stimulating electrode consisting of a metal snap connector, adhesive foam and hydrogel (solid gel) conductive surface.

Intended Use: As a disposable, adhesive, conductive interface between a patient's skin and muscle stimulating devices manufactured by Myotronics-Noromed, Inc. including the Models J4, J5, and BNS-40.

Comparison with equivalent devices: The device is virtually identical to several devices that have previously been legally marketed. K010431 and K961141 (as above) are given as specific examples.

Safety & Effectiveness Information: There are no significant differences between the design and manufacture of the cited equivalent devices. Skin irritation was the only potential hazard identified by risk analysis. Patient contact materials have been tested by an independent testing laboratory and found to be "not an irritant" and to meet pertinent requirements of ISO 10993 (Test results on file.) Effectiveness was demonstrated through impedance testing.

Conclusion: The Myo-trode SG is substantially equivalent to the cited predicate devices, has been certified to meet current standards for irritation, cytotoxicity and allergic potential, and has been tested for effectiveness.